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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,327

10/16/2003

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8506

22827 7590 10/24/2008  
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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

10/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,327	BOGA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008 and 11 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 60, 64, 65, 67-72, 74 and 76-83 is/are pending in the application.
- 4a) Of the above claim(s) 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60, 64-65, 67, 70-72, 74, 76-83 is/are rejected.
- 7) ☒ Claim(s) 68 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1645

### **DETAILED ACTION**

Claims 60, 64-65, 67-72,74,76-83 are pending. Claim 82 stands withdrawn from consideration.

#### ***Continued Examination Under 37 CFR 1.114***

*I.* A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2008 has been entered.

#### ***Rejections Maintained/Response to Arguments***

1. Applicant's arguments filed July 11, 2008 have been fully considered but they are not persuasive.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

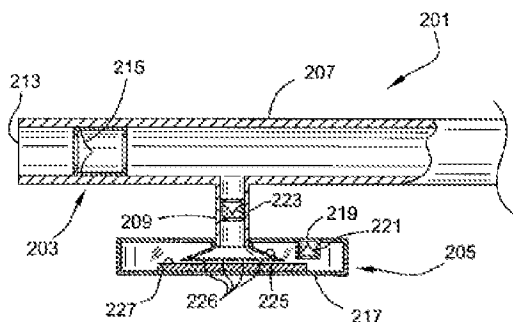
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The rejection of claims 60, 64-65, 67, 71-72,74,76-81 and 83 under 35 U.S.C. 103 as being obvious over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960 is traversed on the grounds that:

Art Unit: 1645

- The ammonia sensing membrane 127 of Pan is attached to the bottom of a container 117 (Figure 2). The visual indicating agent is not disposed in a tubular carrier portion of a breath collecting device through which the breath of the user passes.
  - Tratnyek detects ethylene oxide and has nothing to do with ammonia detection and ammonia is not an alkylating agent.
4. It is the position of the examiner that Applicant traverses Pan based upon a single disclosed embodiment shown in figure 1, but Pan discloses several embodiments, one of which still reads on the claimed invention :

FIG. 5



In Figure 5, the breath testing device (207) that comprises a substrate (227) on which a visual indicating agent is disposed (225, 226, 227) that is sensitive to ammonia and is located with a tubular carrier portion (209 and 205) of the breath collecting device through which the breath of the user passes (breath passes through 209, 223, 205 and out through 219/221). Therefore, the indicating agent of Pan is located within a passage of the tubular carrier portion, specifically a side passage, which has inlet and outlet portions that lead to and from the tubular carrier portion for capturing a gaseous breath sample and for releasing the breath sample. Pan et al teaches [0060] “Any dye that is sensitive to and responds to changes in the amount of ammonia that

Art Unit: 1645

permeates the pores of the polymer may be employed. In a preferred embodiment, the dye is a pH sensitive dye”.

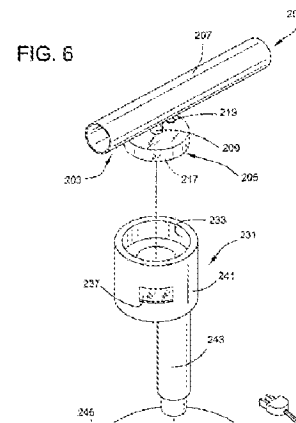
Detail Description Paragraph:

[0068] Referring now to FIGS. 4-6, a breath sampler and optical reader of a second embodiment are generally designated at 201 and 231, respectively (collectively, "a breath sampling system"). The breath sampler 201 comprises a breath handler 203 and a detection unit 205. Corresponding parts of the breath sampler 201 and optical reader 231 will be indicated by the same reference numerals as the breath sampler 101 and optical reader 131 of the first embodiment, plus 100. The construction of the breath handler 203 may be substantially the same as the breath handler 103 of the first embodiment. However, the detection unit 205 is a much flatter container 217 defining a shallow internal volume through which **air passes to a vent 219** and the container does not hold any liquid. **A check valve 221 is located at the vent 219** and a check valve 223 is located in the collection branch 209, as with the first embodiment. The diffuser head 225 has its lower surface disposed just above the ammonia sensing membrane 227 so that the breath sample passes out of dispersed openings 226 and is spread over and contacts the membrane. In this embodiment, the ammonia sensing membrane 227 is operable to detect ammonia directly from the breath sample without passage into a liquid.

- With respect to Applicant traversal to Tratnyek, it is the position of the examiner that Arai et al was cited to show triarylmethane dyes as ammonia indicators. Arai et al clearly names the species triarylmethane dyes for detection of ammonia and Tratnyek was cited for teaching the fact that Michler's hydrol is a known species within the genus of triarylmethane dyes described as an ammonia detection indicators of Arai et al. Applicant's traversal of the rejection of the claims under 35 USC 103 which included the teaching, suggestions and guidance of Arai et al were not addressed.
- With respect to claim 67, the nanoparticle indicator is immobilized in the substrate, Pan describes the following: a substrate (polymeric material and a dye associated with the polymeric material (see page 2, [0011]) with a visual indicating agent disposed therein is one embodiment, also see [0057 "embed or bind the dye to the pores of the polymer"; and [0012]), the pores being from about 0.2 microns to about 9 micrometers, preferably about 2.5 microns or less (see page 5 [0051]) and the dye indicator being in a shape of beads [0056]. When the substrate material has pores that are 0.2 microns, 200 nanometers, the polymeric

material to which the visual indicating agent is immobilized would fit into the 200 nanometer pores (0.2 micron size)), as well as the indicator in the shape of beads would be about 200 nanometers in size .

- With respect to claim 83 which defines the device to comprise a transparent portion, the examiner is providing Figure 6 of Pan to show that a portion of the carrier portion is



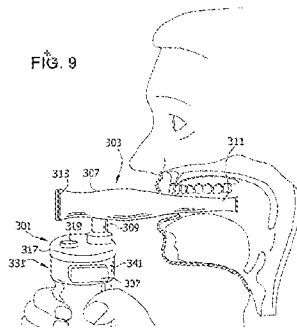
transparent, specifically an output display window (237):

Detail Description Paragraph:

[0070] The smaller, portable optical reader 231 includes housing having a reader portion 241, an **output display 237**, and a handle 243 which houses a rechargeable battery (not shown). The battery allows the optical reader 231 to be self-contained, i.e., operable to provide a reading remote from any other power source. The breath sampler 201 is preferably disposable and constructed for releasable, snap together attachment to the optical reader 231. However, other forms of attachment of the breath sampler 201 to the optical reader 231 may be employed. The optical reader 231 is light weight and portable so that it can be attached to the breath sampler 201 as it is being used by the subject for an immediate indication of an H. pylori infection in the gastrointestinal tract. As shown in FIG. 4, the subject may hold the handle 243 of the optical reader 231 while breathing through the breath sampler 201 mounted on the optical reader. A battery charger 245 is provided for recharging the battery housed in the handle 243 of the optical reader 231 (FIG. 6).

- The breath collected by the device of Pan passes through a tubular carrier portion of the device, through which the breath of the user passes (see figure 9):

Art Unit: 1645



Pan Detail Description Paragraph:

[0074] A breath sampler and optical reader, generally designated at 301 and 331, respectively, are shown in FIGS. 9-12. The breath sampler 301 comprises a breath handler 303 and a detection unit 305. Corresponding parts of the breath sampler 301 and optical reader 331 will be indicated by the same reference numerals as breath sampler 101 and optical reader 131 of the first embodiment, plus 200. The breath handler 301 has a construction similar to that of the breath handler 101, including a tube 307 and a sample collection branch 309. The tube 307 has a mouthpiece end portion 311 and an intake end portion 313 so that air may pass through the tube from an air intake 313A to a breath sample opening 311A in the distal end of the mouthpiece end portion (see FIG. 12). A check valve 315 located in the air intake 313A of the tube 307 restricts flow through the tube at the air intake end portion 313 to a direction toward the mouthpiece end portion 311 and blocks flow out of the tube through the air intake. The check valve 315 may be of any suitable construction, and is illustrated in FIGS. 9-12 as a disk including a rigid, perforated substrate 315A and a flexible diaphragm 315B having a central opening. Upon inhalation, the pressure drop behind the diaphragm 315B pulls it off of the substrate 315A, allowing air to flow in through the holes in the substrate and through the central opening of the diaphragm. Upon exhalation, positive air pressure behind the diaphragm 315B (and the resiliency of the diaphragm) urges the diaphragm against the substrate, covering the holes in the substrate and central hole in the diaphragm to block the flow of air past the check valve 315 out of the tube 307. A check valve 321 is located at a vent 319 in a collection container 317 of the detection unit 305, and a check valve 323 is located in the collection branch 309, as with the first embodiment. These check valves (321, 323) are of the same construction as the check valve 315 and are oriented to permit the flow of air as described above for the breath sampler 101 of the first embodiment. A greater or lesser number of check valves (e.g., valves 315, 321, 323) may be used without departing from the scope of the present invention. For example and without limitation, the check valve 321 at the vent 319 might be omitted. A lower end of the collection branch 309 includes a breath sample outlet 310 which opens into liquid L covering the membrane 327 (FIG. 12). It will be understood that the breath sampler 301 may operate without the liquid L and not depart from the scope of the present invention.

Art Unit: 1645

Detail Description Paragraph:

[0077] The collection branch 309 is received in the collection container 317 through an opening 317A and is pivotable in the opening with respect to the collection container about the axis of the collection branch. It is preferable to have the air intake 313A of the breath handler 303 offset from (i.e., not located directly above) the vent 319 so that as the subject breathes in and out several times through the breath handler 303, the subject does not inhale the material expelled from the collection container 317 through the vent. FIG. 11 illustrates two positions of the breath handler 303 with respect to the collection container 317. These two positions may be achieved by turning the breath handler 303 within the collection container 317. Thus, when the subject grasps the handle 343 of the optical reader 331 with either hand, the breath handler 303 may be turned relative to the collection container 317 to offset the air intake 313A of the breath handler from the vent 319 while allowing the optical reader to be held in a comfortable position for receiving the mouthpiece end portion 311 into the mouth. It is to be understood that the offset may be achieved in other ways (e.g., without pivoting of the breath handler) without departing from the scope of the present invention.

Pan in view of Arai and Tratnyek still obviate the instantly claimed invention as now claimed.

5. The rejection of claim 70 rejected under 35 U.S.C. 103(a) as being unpatentable over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960, as applied to claims 60, 64-65, 67, 71-72, 74, 76-81 and 83 above, further in view of US Pat. 7,052,854 was not traversed in the Remarks submitted. The rejection is maintained for reasons of record, and responses set forth above. US Pat. 7,052,854 teach and show nanoparticles of silica and alumina with a color indicator attached on the surface of the nanoparticles for detecting the biomarker ammonia in an analogous art for the purpose of defining nanostructure-based assemblies in combination with sensor technology to provide an efficient and accurate means for identifying the presence of a target analyte/biomarker in a sample of bodily fluid (see title, abstract, paragraphs detailed description ([10 (ammonia)], [claim 6 (ammonia)], [43 (ammonia)] [14 and 047, breath sample[018], 53 (silica) and 68 (alumina)])



***New Grounds of Rejection/Objection***

***Allowable Subject Matter***

6. Claims 68 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 83, a non-originally presented claim, recites the phrase “at least a portion of the carrier portion is transparent”. Upon consideration of the disclosure in the instant Specification, the examiner found at [0038] the phrase “substantially transparent”. The phrase “substantially transparent” was not defined to be any specific portion of the claimed carrier portion, and therefore does not provide original descriptive support for the combination of claim limitations recited in claim 83. Applicant’s specification defines the instantly claimed device in a kit to be made out of glass or plastic, materials that are transparent. Claim limitations consistent with the

Art Unit: 1645

disclosure in the instant Specification could be used to obviate this New Matter rejection. Claim 83 recites New Matter for the reasons set forth above.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references are being cited to show indicator dyes.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.

The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Shanon Foley or Robert Mondesi can be reached on 571-272-0898 or 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/  
Examiner, Art Unit 1645  
October 22, 2008

/Mark Navarro/  
Primary Examiner, Art Unit 1645